

REMARKS

The Office Action

Claims 11, 13-20, 22, 24, 26, 28, 33-41, and 43 were pending in this application. Claims 1-10, 12, 21, 23, 25, 27, 29-32, and 42 were previously canceled. With this reply new claims 44-46 have been added. Thus, with the reply claims 11, 13-20, 22, 24, 26, 28, 33-41, 43, and 44-46 are pending in this application. Claims 33-35 and 37-40 are allowed. Claims 11, 13-20, 22, 24, 26, 28, 36, 41, and 43 stand rejected under 35 U.S.C. § 102(b). This rejection is addressed below.

Rejection under 35 U.S.C. § 102(b)

Claims 11, 13-20, 22, 24, 26, 28, 36, 41, and 43 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Thatcher et al., U.S. Patent No. 5,807,847 (hereafter “Thatcher”). Applicants have addressed this rejection by amendment of the claims and with the following remarks.

The present rejection is based upon inherency, as the office action states at page 4: “sedation or mitigation of anxiety would be inherent. Moreover, the patient population being treated in the claims and prior art overlap.” Applicants respectfully disagree with this analysis.

Thatcher teaches the administration of nitrate esters for the relaxation of tissues. Thatcher does not teach or suggest that nitrate esters be administered to patients suffering

from anxiety or sleeplessness. Nor does Thatcher teach or suggest that nitrate esters can be used to reduce anxiety, aid sleep, or induce sleep.

Applicants have amended the claims to expedite prosecution. As amended, claims 11, 13-20, 22, 24, 26, 28, 36, 41, and 43 are directed to methods for reducing anxiety, aiding sleep, or inducing sleep in a patient in need thereof. The claims have been amended to clarify that the patient populations being treating by the instant claims are different from the patient population being treated by Thatcher. These amendments are not a surrender of the originally claimed subject matter. Applicants reserve the right to pursue the originally claimed subject matter in a continuation application.

In order for a claim to be anticipated, a prior art reference must teach each and every limitation of the claim (M.P.E.P. § 2131). While recognizing that the treatment of anxiety is not explicitly anticipated by the cited art, the Office rejects this subject matter arguing that Thatcher inherently teaches such treatment. Regarding inherency, M.P.E.P. § 2112 states:

“To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (emphasis added).

Applying this standard to the present case, the cited references do not inherently anticipate claims 11, 13-20, 22, 24, 26, 28, 36, 41, and 43, as amended.

The Office notes that the patient population being treated by Thatcher and in the

present claims overlap. Even if this were true, however, the existence of overlapping patient populations, by itself, is irrelevant to inherency. As stated above, inherency requires that the claimed invention is necessarily present in the prior art. The Office's own arguments clearly recognize that the use of nitrate esters for vasodilation as described by Thatcher does not necessarily reduce anxiety, aid sleep, or induce sleep as these patient populations are merely overlapping and not identical. As stated above, "the mere fact that a certain thing may result from a given set of circumstances is not sufficient" (M.P.E.P. § 2112) to provide an inherent teaching.

In sum, Thatcher does not inherently teach a treatment for anxiety or sleeplessness because the treatments disclosed by Thatcher do not necessarily involve treatment of anxiety or sleeplessness.

In view of the amendments to the claims and the remarks above, the rejection of claims 11, 13-20, 22, 24, 26, 28, 36, 41, and 43 for anticipation by Thatcher should be withdrawn.

Applicants have added new claims 44-46 which are directed to methods for providing sedation or anesthesia in a subject in need thereof. None of the compounds recited in claims 44-46 are disclosed in Thatcher. Accordingly, claims 44-46 are novel over Thatcher.

Support for amended and new claims

Claims 11, 13, 33, 36, 37, and 40 have been amended to recite methods for reducing anxiety, aiding sleep, or inducing sleep. Support for using the compounds of the invention for reducing anxiety, aiding sleep, or inducing sleep is found in the specification at page 18, lines 5-27.

Support for new claims 44-46 is found in the specification from pages 22-38 (reciting compounds) and at page 18, lines 5-9 (reciting the use of compounds of the invention to provide sedation or anesthesia).

CONCLUSION

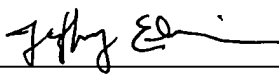
Enclosed is a Petition to extend the period for replying to the Office action for three months, to and including January 30, 2006 (because January 29, 2006 falls on a Sunday), and a check in payment of the required extension fee.

Applicants submit that the claims are in condition for allowance, and such action is requested. If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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